

## "Summary of Safety & Effectiveness"

MAR - 6 1998

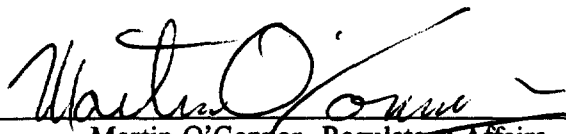
AimStep™ Pregnancy is intended for the qualitative identification of hCG (human Chorionic Gonadotropin) in urine to aid in the early determination of pregnancy. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG. The assay is conducted by dipping the test strip into urine and observing for the formation of colored bands. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate and form a colored band on the Specimen portion of the membrane. Absence of this colored band suggests a negative result. To serve as a procedural control, a colored band at the Control Zone will always appear regardless of the presence or absence of hCG.

A multi-center clinical evaluation was conducted comparing the results obtained using AimStep™ Pregnancy and another commercially available test. The study included 148 urine specimens tested with both assays. The following results were found:

	Positive Results	Negative Results
AimStep™	64	84
Commercially Available Test	64	84

AimStep™ Pregnancy showed a 100% concordance with the other commercially available test.

AimStep™ Pregnancy detects hCG concentrations of 20 mIU/ml and greater. The test has been standardized to the World Health Organization Third International Standard. The addition of hLH (300 mIU/ml), hFSH (1000 mIU/ml), and hTSH (1000 µIU/ml) to negative (0 mIU/ml hCG) and positive (20 mIU/ml hCG) urine showed no cross-reactivity.



Martin O'Connor, Regulatory Affairs  
Germaine Laboratories, Inc.  
4203 Gardendale Center, Suite 230  
San Antonio, TX 78229 USA

2-9-98

Date

Premarket Notification 510(k) Number



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAR - 6 1998

Martin O'Connor  
General Manager  
Germaine Laboratories, Inc.  
4203 Gardenale Center  
Suite 230  
San Antonio, Texas 78229

Re: K980531  
AimStep™ Pregnancy  
Regulatory Class: II  
Product Code: JHI  
Dated: February 9, 1998  
Received: February 11, 1998

Dear Mr. O'Connor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

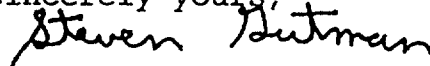
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use

510(k) Number: K 980531

Device Name: AimStep™ Pregnancy

"Indications For Use" - AimStep™ Pregnancy is intended for the qualitative identification of hCG (human Chorionic Gonadotropin) in urine to aid in the early determination of pregnancy. This test is for professional use.

(Please do not write below this point)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K 980531

Prescription Use ☒  
(per 21 CFR 801.109)

or

Over-The-Counter Use ☐